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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,000	04/19/2001	Vi-En Choong	A-70204-1/RMS/BTC	5054

23330 7590 11/28/2003

MOTOROLA, INC.
CORPORATE LAW DEPARTMENT - #56-238
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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,000	CHOONG ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-19,21-24,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19,21-24,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The use of the trademark TRITON X-100 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

2. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 15-19, 21-24, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

5. For convenience, claims 15 and 22, the only independent claims, are reproduced below.

15. (currently amended) A method for enhancing nucleic acid hybridization [in a device having one or a plurality of microlocation(s), each microlocation comprising a nucleic acid probe present on a substrate], said method comprising the steps of:

providing a substrate, said substrate comprising one or a plurality of microlocation(s), each microlocation comprising a DNA probe present on said substrate;

providing a buffer present on or surrounding said microlocation(s);

providing two or more electrodes adapted to receive charge, said two or more electrodes being separated from one another, from said microlocation(s) and from said buffer, but appropriately positioned so as to create an electric field in said microlocation(s) without creating current flow in said microlocation(s) when said two or more electrodes receive charge;

providing an electrical source operatively associated with the electrodes for providing charge to said electrodes;

[(a)]applying a sample comprising [one or more nucleic acids] DNA to said microlocation(s); and

[(b)]applying charge to said [device]electrodes [to produce an electric field at said microlocation(s) without creating current flow in said microlocation(s), and] such that said [one or more nucleic acids are] DNA sample is transported to said [nucleic acid] DNA probes present at said microlocation(s) under conditions sufficient for hybridization to occur.

22. (currently amended) A method for enhancing nucleic acid hybridization [in a device having one or a plurality of microlocation(s) present on a substrate, each microlocation comprising a nucleic acid probe], said method comprising the steps of:

providing a substrate, said substrate comprising one or a plurality of microlocation(s), each microlocation comprising a DNA probe present on said substrate;

providing a buffer present on or surrounding said microlocation(s);

providing two or more electrodes adapted to receive charge, said two or more electrodes being separated from one another, from said microlocation(s) and from said buffer, but appropriately positioned so as to create an electric field in said microlocation(s) without creating current flow in said microlocation(s) when said two or more electrodes receive charge;

providing an electrical source operatively associated with the electrodes for providing charge to said electrodes;

[(a)]applying a sample comprising [one or more nucleic acids] DNA to said microlocation(s);

[(b)]applying charge to said [device] electrodes [to produce an electric field at said microlocation(s) without creating current flow in said microlocation(s), and] such that said [one or more nucleic acids are] DNA sample is transported to said [nucleic acid] DNA probes at said microlocation(s) under conditions sufficient for hybridization to occur; and

[(c)]applying charge to said [device] electrodes [to produce an electric field at said microlocation(s) without creating current flow in said microlocation(s), and] such that [said one or more nucleic acids] at least one DNA component corresponding to said DNA sample that [are] is not hybridized with said [nucleic acid] DNA probes [are] is transported away from said [nucleic acid] DNA probes at said microlocation(s).

6. For purposes of examination, claims 15 and 22, and claims that depend therefrom, have been interpreted as encompassing embodiments where any voltage is used. Said claims have also been interpreted as taking on any configuration and having from two to an infinite number

of electrodes. Said claims have also been interpreted as encompassing the electrodes coming into contact with the substrate and/or buffer and/or sample.

7. A review of the disclosure, however, fails to find support or the breadth f the scope of claims now before the Office. With regard to the number and configuration of electrodes, the specification has been found to provide a description of where from two to six electrodes are used, and then they are of a predetermined configuration. In support of this position, attention is directed to page 14 of the specification, which is reproduced in part below.

> In terms of particularly preferred configurations, the invention provides a device, desirably wherein:
>
> (a) two electrodes are present, and the electrodes are on opposite sides of the substrate in a stacked arrangement;
>
> (b) three electrodes are present, and the electrodes form a triangle in one plane, having a center in the plane, with the substrate located in the center;
>
> (c) four electrodes are present, and the electrodes form a square in one plane, having a center in the plane, with the substrate located in the center;
>
> (d) five electrodes are present, and the electrodes form a pentagon in one plane, having a center in the plane, with the substrate located in the center;
>
> (e) five electrodes are present, and the electrodes form a three dimensional triangle, having a center in the triangle, with the substrate located in the center (i.e., desirably at the center of all three dimensions);
>
> (f) six electrodes are present, and the electrodes form a hexagon in one plane, having a center in the plane, with the substrate located in the center; or
>
> (g) six electrodes are present, and the electrodes form a three dimensional square, having a center in the square, with the substrate located in the center (i.e., desirably at the center of all three dimensions of the square).

In addressing the strength of the electric field, attention is directed to page 14, last two lines, bridging to page 15 of the specification; reproduced below.

> **power supply (i.e., a battery), and a transformer. Generally, to establish the electric field, from at least about 200 volts/cm to at least about 10,000 volts/cm must be delivered by the power supply.**

In addressing the aspect of to what extent the electrodes come into contact with the substrate, the buffer and/or the sample, attention is directed to page 15, last paragraph; reproduced below in part.

> **and decreases cost. Third, since the electrodes do not come into contact with the sample, with the substrate, and/or with the buffer (if buffer is present), any unwanted or unexpected reaction between the electrodes and the sample, between the electrodes and the substrate, and between the electrodes and the buffer solution, is avoided. The**

Acknowledgement is made of where applicant, at page 16 states in part:

> Many other system configurations in the spirit and scope of the present invention can be employed, and would be apparent to those skilled in the art based on the specification disclosures.

It would appear that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

8. In view of the apparent breadth of the claims, the explicit statements as to how the claimed method is to be performed and how the device so used in the method is configured, applicant is urged to consider narrowing the scope of the claims such that the claims more closely parallel the embodiments set forth in the original disclosure.

9. Claims 15-19, 21-24, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co.*,

Ltd., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

10. For purposes of examination, claims 15 and 22 have been interpreted as encompassing embodiments where a "buffer" is provided and it "surrounds" the area of the sample, yet is not in contact with the sample. As presently worded, the sample, though in contact with a probe bound to a substrate, is not required to be in contact with a "buffer," which has been interpreted as encompassing a hybridization buffer. Accordingly, hybridization will not take place.

11. Claims 15 and 22 also require that the DNA sample be "transported" to the nucleic acid probes. As presently worded, only one DNA probe need be present and the sample is placed on the probes. Note language of claim 15 which requires "applying sample comprising DNA to said microlocations" and that "each microlocation compris[es] a DNA probe." The specification does not enable transport of DNA sample when the DNA sample is not required.

Conclusion

12. Rejections that appeared in the prior Office action and which were not repeated hereinabove have been withdrawn.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
November 23, 2003